REMARKS

This responds to the Office Action dated 7 September 2010. Claims 1-37 are pending in the application, although claims 31-37 have been withdrawn. Claims 12 and 20 are amended. Support for the amendments is provided by at least FIGS. 3 and 6 and the description at page 7 of the present application. New claims 38-41 have been added. No new matter has been added.

Claim Rejections – 35 U.S.C. §103

Claims 1-30 stand rejected under 35 U.S.C. § 103(a) as being impatentable over U.S. Patent No. 5,545,178 to Kensey et al. in view of U.S. Published Application No. 2002/0183787 to Wahr et al. and U.S. Published Application No. 2003/0176890 to Buckman et al. Applicant respectfully traverses this rejection.

Claim 1 recites "an anchor . . . attached to the filament at a first end of the closure device; . . . a locking apparatus separate from the filament, anchor, and sealing plug . . . , wherein the locking apparatus comprises a ratchet mechanism, the ratchet mechanism including a first member that maintains a fixed position relative to the filament, and a second member that is movable along the filament relative to and in contact with the first member and configured to apply a pressure to the sealing plug."

Claim 12 as amended recites "a filament attached to the internal component, the external component being slidable along the filament toward the internal component; a locking apparatus that is separate from the internal and external components and the filament, . . . wherein the locking apparatus comprises a ratchet mechanism, the ratchet mechanism including a first member that maintains a fixed position relative to the

filament and the internal component, and a second member that is movable relative to and in contact with the external component and configured to apply a pressure to the external component."

Claim 20 as amended recites "a filament attached to the anchor and the sealing plug being slidable along the filament toward the anchor; a one-way lock . . . being separate from the carrier tube, anchor, filament, and sealing plug, wherein the one-way lock comprises a ratchet mechanism, the ratchet mechanism including a first member that maintains a fixed position relative to the anchor, and a second member that is movable relative to and in contact with the first member to compress the sealing plug toward the anchor."

Claim 28 recites "an anchor for insertion through the internal tissue wall puncture attached to the filament at a first end of the closure device; a strap and locking hub attached to the filament adjacent to the anchor . . . ; a sealing plug disposed at least partially about the strap and adjacent to the locking hub, wherein the strap and hub comprise a ratchet mechanism configured to apply a pressure to the sealing plug to compress the sealing plug along the strap toward the anchor."

Kensey discloses with reference to FIGS. 1-5 a device 20 used to close and seal a tissue puncture. The device 20 includes a sealing member 36, an anchoring member 38, a holding member 40, and a positioning filament 42 that interconnects the features 36, 38, 40. The holding member 40 is constructed as a disc that slides along the filament 42 to compress the sealing member 36 toward the anchoring member 38 (*see* FIGS. 6 and 7). The holding member 40 is held in place after compressing the sealing member 36 by

positioning a knot in one strand of the filament 42 on a proximal side of the holding member 40 and tying off the opposite strand of the filament 42 outside of the tissue layer (*see* FIG. 5 of Kensey). The holding member 40 is a single-piece device that is void of a ratchet mechanism. Furthermore, the holding device 40 moves in its entirety toward the anchor along the filament 42 to compress the sealing member 36. The holding member 40 is always positioned proximal of the sealing member 36 and does not at any time pass through any portion of the sealing member 36. There is no disclosure or suggestion by Kensey of combining the holding member 40 with any other feature to assist in compressing the sealing member 36 or maintaining the sealing member 36 in a compressed state. Further, there is no disclosure or suggestion by Kensey of connecting the anchoring member 38, sealing member 36 and holding member 40 together with anything but the filament 42.

Wahr discloses with reference to FIGS. 1 and 11 a closure device 10 that includes an anchor 12 directly connected to a tether 16. The tether 16 extends through and connects to a second anchor 14 via a releasable fixation mechanism 30, which is fixed to the second anchor 14. When released, the releasable fixation mechanism 30, permits the second anchor 14 to move along the tether 16 relative to the first anchor 12. When locked, the releasable fixation member 30 fixes a position of the second anchor 14 relative to the first anchor 12.

The Wahr apparatus fails to disclose separate features of a filament, an anchor, a sealing plug, and a two-piece locking apparatus as set forth in each of independent claims 1, 12, 20 and 28. Wahr fails to disclose at least a sealing plug and filament that are

separate from the anchors 12, 14 and the fixation member 30. There is no need for a separate filament since the tether 16 is directly connected to the anchor 12. Further, the anchors 12, 14 are intended to directly contact tissue surfaces on opposite sides of a tissue opening to assist in holding a septum primum (SP) against a septum secundum (SS) (*see* FIGS. 9-10). There is no disclosure or suggestion by Wahr to use the closure device 10 to compress a sealing plug. As noted by the Examiner, Wahr also fails to disclose any kind of specific ratchet structure, but instead only generally suggests a ratchet mechanism.

Buckman fails to remedy the deficiencies of Wahr and Kensey as they relate to claims 1, 12, 20 and 28. Buckman discloses a ratchet device that includes a bolt 10 having a plurality of serrations 20 along at least one of its ends 18, and a pressure plate 26 with ratcheting lock 28 that ratchets along the serrations 20. There is no disclosure or suggestion by Buckman of using a ratchet mechanism in combination with a filament, anchor, sealing plug, or two-piece locking apparatus. Thus, Buckman suffers from the same deficiencies as Wahr and Kensey as they relate to independent claims 1, 12, 20 and 28.

Furthermore, the tether 16 disclosed by Wahr and the bolt 10 disclosed by Buckman are comparable in some respects to the claimed filament in that the anchor 12 is attached to the tether 16 in Wahr and the pressure plate 26 is attached to the bolt 10 in Buckman. However, both Wahr and Buckman fail to disclose or suggest a separate component from the tether 16 and bolt 10 for operation of the ratchet feature. The Examiner contends that "one skilled in the art would have a choice between providing a

separate ratchet strap (similar to the strap disclosed in Buckman) along the filament 42, or alternatively, to integrally form ratchet teeth along the filament 42 itself so as to form a ratchet strap that is integral with the filament 42" of the Kensey device. Applicant respectfully disagrees.

First, there would be no motivation for one of skill in the art to form ratchet teeth in the filament 42 of Kensey because such a modification, assuming *arguendo* it were possible, would cause significant structural degradation to the filament 42, and because a filament by its very structure is akin to a piece of thread that is intended to slide through the sealing plug 36 and anchor 38 (and holding member 40), which sliding function would be hindered if the filament 42 included ratchet features.

Further, in order to modify Kensey, one of skill in the art would have to replace the two strands of filament 42 and the holding member 40 with one of the ratchet devices disclosed by Wahr or Buckman. Attaching the anchor to a filament as set forth in the claims rather than with a strap or bolt as disclosed in Wahr and Buckman has certain advantages. At least FIGS. 1B and 2 of the present application illustrate how the anchor 108 is able to rotate into different positions during operation of the device due in large part to the filament connection. The anchor 108, if attached directly to the strap and bolt structures disclosed by Wahr and Buckman, would have significantly limited movement, in particular into the position required for delivery into a vessel as shown in FIG. 1B. The combination of a filament with a locking apparatus having first and second members as set forth in claims 1, 12, 20 and 28 is novel and distinguishes the claimed invention from the art of record.

Thus, Applicant submits that Kensey, Wahr and Buckman fail to disclose or suggest every limitation of claims 1, 12, 20 and 28 for at least the reason they fail to disclose or suggest attachment of an anchor to a filament, and a separate locking apparatus (with first and second members) from the filament.

Further to the above, Applicant submits that one of ordinary skill in the art reviewing Kensey would have no motivation to replace the single-piece holding member 40 of Kensey with a two-piece locking apparatus having a ratchet mechanism as set forth in the independent claims. Furthermore, there is no motivation for one of skill in the art to replace the single-piece holding member 40 taught by Kensey with a two-piece locking apparatus as set forth in the claims, or to maintain a first member of the two-piece locking apparatus in a fixed position relative to the filament and move the second member along the filament relative to and in contact with the first member, as recited in respective claims 1, 12, and 20.

In view of the foregoing, Applicant submits that Kensey, Wahr and Buckman, alone or in combination, fail to disclose or render obvious every limitation of independent claims 1, 12, 20 and 28, and the claims that depend from them.

Conclusion

For at least the foregoing reasons, Applicant believes that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicant respectfully requests a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicant invites the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Applicant expressly disclaims all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 08-2623.

Respectfully submitted,

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